### CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit. Account No. 14-1263.

# **ADDITIONAL FEES**

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

# REMARKS

Claims 11-20 are pending in the application.

All claims are rejected for allegedly not being enabled by the specification; allegedly anticipated by Thornfeldt; and allegedly being obvious over Thornfeldt in view of Matsumura et al.

## **Enablement**

Applicants respectfully disagree with Examiner's rationale for raising this rejection.

The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP § 2164. (Emphasis added).

In the present case Examiner asserts that because the synthetic methods for preparing the relevant alkyl-oligosaccharides, or their commercial sources are not disclosed, the claims are enabled only for Orarnix NS and plantarene 1200. As stated in

the MPEP, the enablement requirement only requires that persons in the art be able to practice the invention using the specification and knowledge in the art. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." MPEP § 21264, citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

The compounds used in the claimed methods are well known in the art, and have been made commercially available by numerous chemical suppliers for many years. Examiner has himself applied references disclosing similar compounds from the group of alkyl oligosaccharides. Accordingly, obtaining these compounds cannot reasonably be viewed as requiring undue experimentation.

A patent need not teach, and preferably omlts, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). MPEP § 2164.01.

Further, we bring to Examiner's attention US 6,727,280 that he previously allowed, and which eventually issued on April 27, 2004. The claims were directed to a method of treating colorectal cancer with taxane-containing compositions. The synthesis of not even one of the compounds was disclosed. Further, the source for only one out of a very large number of compounds was provided. This was also true for other components of the compositions. However, the Examiner apparently believed the claims fully enabled, most likely because the compounds were old in the art. In view of the fact that the same facts arise in this case, the same result should be obtained.

In sum, the specification enables the claims so as to be practiced within their entire scope. Unless Examiner can provide a line of technically sound reasoning to explain the alleged undue experimentation of obtaining these compounds, the rejection should be withdrawn.

#### Anticipation

Applicants respectfully disagree with Examiner that Thornfeldt anticipates the claims. However, to expedite the matter, the claims have been amended by deleting references to acyl saccharides.

Thornfeldt teaches and discloses the use of monoaliphatic amines or aliphatic monocarboxylic acid and/or their esters and/or amides as a topically applied composition to treat various skin conditions. See Abstract, and claims 6 and 9. A single reference to the sub-genus of sucrose esters is disclosed. Thornfeldt's compounds do not structurally resemble alkylated mono- or oligosaccharides.

Withdrawal of the anticipation rejection is respectfully requested.

# **Obviousness**

The Applicants believe that the amended claims are not obvious over Thornfeldt because this reference does not teach or suggest the use of alkyl saccharides. Further, there is no evidence or teaching that the acyl and alkyl saccharides are equivalents or freely interchangeable.

Similarly, the amended claims are not obvious over the combined teachings of Thornfeldt and Matsumara. Although Matsumara's compounds have been shown to have antibacterial activity among several microorganisms, this is insufficient to conclude that the compounds would demonstrate this activity with other genera of microorganisms. Persons with ordinary skill in the art would not have a reasonable expectation of success in demonstrating antimicrobial effects in Propionibacterium.

Therefore, substituting Matsumara's alkylglycosides according to Thornfeldt's compositions merely reaches the level of obvious to try, which is below the threshold required for maintaining an obviousness rejection. Examiner's rationale would be easier to support had the claimed method been toward a treatment of Staphylococcus or Salmonella infections. These bacteria were tested by Matsumara. However, the claims are directed to Propionibacterium, which was not even mentioned by Matsumara.

Accordingly, the suggestion to treat Propionibacterial acne with alkylglycosides is not remotely suggested, especially in view of the fact that Thomfeldt's exemplified embodiments are limited to glyceryl esters which are not structurally similar to glycoside esters. Thus, the suggestion that persons of skill in the art would have a reasonable expectation of success in treating Propionibacterial acne is absent.

For these reasons, it is respectfully requested that the rejection under § 103 be withdrawn.

Respectfully Submitted,

Norris, McLaughlin & Marcus 220 East 42 nd Street New York, NY 10017 Telephone (212) 808-0700 Facsimile (212) 808-0844

Theodore Gottlieb, PhD Reg. No. 42, 597 Certificate of Transmission

I hereby certify that this correspondence is being transmitted by facsimile to the U.S. Patent and Trademark Office Fax No. (703)872-9306

on June 30, 2004, (Date)

Theodore Gottlieb

Typed or printed name of transmitte

Signature